K052021

AUG 17 2005

SECTION 11

510(k) Summary of Safety and Effectiveness

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
Mountain View, California 94039-7393

Contact Person: Iskra Mraković
Manager, Regulatory Affairs
Telephone: (650) 694-5004
Fax: (650) 943-7053

Submission Date: July 25, 2005

Device Name: V5Ms Transesophageal Transducer
MPT7-4 Multiplane Transesophageal Transducer

Common Name: Diagnostic Ultrasound Transducers

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

21 CFR 892.1550

	FR #	Product Code
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Predicate Devices:

V5M TEE transducer has already been cleared on the following ACUSON ultrasound platforms:

- ACUSON Sequoia™ ultrasound system (#K051139)
- ACUSON Cypress™ ultrasound system (#K042055)
- ACUSON CV70™ cardiovascular systems (#K042770)

MPT7-4 TEE transducer has already been cleared on the following SONOLINE ultrasound platform:

- SONOLINE G60S™ ultrasound system (#K040060)

Device Description:

The **V5M/MPT7-4** transducers consist of a gastroscope control housing where nosepiece articulation and transducer rotation are controlled. A flexible transesophageal guide tube with a nosepiece containing the acoustic array extends from one end of the control housing and the system cable/connector extends from the other end. The acoustic array has 64 elements and rotates 180 degrees to provide imaging planes from transverse view to inverse transverse view. Rotation is powered by a motor in the control housing and is controlled by the operator using a switch button on the control housing for clockwise and counterclockwise rotation. Nosepiece articulation is achieved by manipulating a vertebrae section adjacent to the nosepiece through a series of control wires attached to knobs on the control housing. The nosepiece can be articulated in both the anterior/posterior and left/right directions.

Intended Use:

1. **V5M** trans-esophageal echocardiograph (TEE) ultrasound transducer and **MPT7-4** multiplane trans-esophageal echocardiograph (TEE) ultrasound transducer are intended primarily for cardiology applications.

   1.1. ACUSON Sequoia™ Ultrasound System is intended for use in the following applications:

   General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid, penis and prostate), Neonatal/Adult Cephalic, Cardiac (adult, pediatric, and neonatal), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-sceletal (superficial and conventional) applications, and intended uses as defined in the FDA guidance document.

   The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

   1.2 ACUSON Cypress™ Ultrasound System is intended for use in the following applications:

   General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (cardiac), Pediatrics, Neonatal Cephalic, Cardiac (adult, pediatric), Trans-esophageal,

Peripheral Vessel, Intra-luminal and Intra-cardiac applications, and intended uses as defined in the FDA guidance document.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

1.3 ACUSON CV70™ Cardiovascular System is intended for the following applications:

Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Intracardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Intracascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

1.4 SONOLINE G60S™ Ultrasound System is intended for the following applications:

Abdominal, Intraoperative, Small Parts, Transcranial, OB/GYN, Cardiac, Transesophageal, Pelvic, Neonatal/Adult Cephalic, Vascular, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The **Sequoia Ultrasound System, the Cypress Ultrasound System, the CV70 Cardiovascular System, and the G60S Ultrasound System** have been designed to conform to the following *product safety standards*:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-2, 1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Device Directive
- Safety and EMC Requirements for Medical Equipment

- EN 60601-1
  - EN 60601-1-1
  - EN 60601-1-2
  - EN 60601-1-37
- ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing

The systems' acoustic output is in accordance with ALARA principle (as low as reasonably achievable)

Technological Comparison to Predicate Devices:

V5M TEE ultrasound transducer is substantially equivalent in its technology and functionality to the V5M TEE transducer which is already cleared under the following 510(k) premarket notification numbers: K051139 (ACUSON Sequoia ultrasound system), K042055 (ACUSON Cypress ultrasound system), and K042770 (ACUSON CV70 cardiovascular system).

MPT7-4 TEE ultrasound transducer is substantially equivalent its technology and functionality to the MPT7-4 TEE that is already cleared under the following 510(k) premarket notification number: K040060 (SONOLINE G60S ultrasound system).

Remaining of the page left blank intentionally.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2005

Ms. Iskra Mraković
Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
Ultrasound Division
1230 Shorebird Way
P.O. Box 7393
MOUNTAIN VIEW CA 94039-7393

Re: K052021
Trade Name: V5Ms Transesophageal Transducer and MPT7-4 Multiplane Transesophageal Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: July 25, 2005
Received: July 29, 2005

Dear Ms. Mraković:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the MPT7-4 Multiplane Transesophageal Transducer intended for use with the SONOLINE G60 S Ultrasound System and the V5Ms Transesophageal Transducer intended for use with the ACUSON CV70 Cardiovascular System, ACUSON Sequoia Diagnostic Ultrasound System, and ACUSON Cypress Ultrasound System as described in your premarket notification.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **MPT7-4** Multiplane Transesophageal Transducer for use with: **SONOLINE G60 S Ultrasound System**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 2,3,7
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: breast, testes, thyroid, penis, prostate, etc.
Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging
Note 4 B&W SieScape panoramic imaging
Note 5 Power SieScape panoramic imaging
Note 6 For example: abdominal, vascular
Note 7 Contrast agent imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052021

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5Ms** Transesophageal Transducer for use with:
ACUSON CV70 Cardiovascular System

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal		P	P	P	P	P	P		BMDC	Note 2,3
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA (K032111); E = added under Appendix E

Note 2 Ensemble tissue harmonic imaging
Note 3 3D imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052021

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5Ms** Transesophageal Transducer for use with **ACUSON Sequoia Diagnostic Ultrasound System**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophtalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*	P	P
Small Organ (Specify)**											
Neonatal Cephalic											
Adult Cephalic											
Cardiac			P	P	P	P	P		P*	P	P
Trans-esophageal			P	P	P	P	P		P*	P	P
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)***											

P=Previously cleared by the FDA under premarket notification K051139, K041319, K032114, K022567, K002807, and K973767.

Additional Comments:
*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+Color Doppler, B+PWD+ Color Doppler, B+CWD+ Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLESE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052021

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V5Ms** Transesophageal Transducer for use with **ACUSON Cypress Ultrasound System**

Intended Use: Diagnostic imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Note 1)		P	P	P	P	P	P			Note 3
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P			Note 3,4
Transesophageal		P	P	P	P	P	P			Note 3,4
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Note 1 For example: cardiac
Note 3 Harmonic imaging
Note 4 Contrast agent imaging

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052021